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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,757	06/25/2001	John E. Ahern	B0410/7282D1	2885

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,757

Applicant(s)

AHERN ET AL.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-31 is/are pending in the application.
- 4a) Of the above claim(s) 19, 25 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-24 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 19-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 4. 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 19, drawn to a pellet, classified in class 424, subclass 422.
- II. Claims 20-31, drawn to an apparatus, classified in class 604, subclass 57.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as an injector for a fluid. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

If invention II is elected then this application contains claims directed to the following patentably distinct species of the claimed invention regarding the delivery chamber:

1. Figures 2A,2B and 4A, or
2. Figures 3A, #B and 4B.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 20-23,26 and 29-30 are considered generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with John Perullo on 12/11/03 a provisional election was made with traverse to prosecute the invention of II, claims 20-31. Affirmation of this election must be made by applicant in replying to this Office action. Additionally, species 1 was elected which corresponds to claims 20-24, 26-30. Claims 19, 25 and 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The two PTO-1449(s) have been entered into the application and reviewed. However, some of the references are contained within the parent application (08/993,586). This file has been ordered from the repository and the references not yet reviewed will be initialed on the next correspondence when the parent file application has been received.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-21, 23-24, 26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (US Pat# 4,588,395). Lemelson discloses an elongate flexible body (31), a delivery chamber (32) with a space and a port, and an actuator (17). The device also includes a control mechanism (20) and a plunger (36). The device is disclosed for use in arteries; therefore, its diameter is dimensioned small enough to traverse the vessels leading from the heart of a patient thereby making it small enough to enter the larger atrium and/or ventricles of the heart. See 2:35. The delivery chamber, as shown in figures 1,2 and 3 is substantially a cylindrical housing

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which is dimensioned to store a plurality of minispheres. Even though only one implant is shown within the delivery chamber, the length of the chamber clearly shows that the chamber is capable of housing multiple smaller implants in axial alignment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Matsuno et al (US Pat# 5,342,394). Lemelson meets the claim limitations as described above and additionally discloses that the invention (catheter) is inserted into an animal or human body and “manipulated so as to provide the head end of the device at a fixed location within the body”. Yet, Lemelson fails to include a steering mechanism.

However, Matsuno discloses a catheter that includes a flexible body (1) with an actuator (14) and also includes a steering mechanism (31). See Figure 9.

At the time of the invention, it would have been obvious to incorporate the steering mechanism of Matsuno into the invention of Lemelson. The devices are analogous to each other and also the claimed invention; therefore, a combination is proper. Additionally, Lemelson makes reference to “manipulating” the device to a fixed location in the body. It is well known in the vascular catheter art that steering mechanisms ease the manipulating of tubular flexible bodies (catheters) to fixed locations within a patient’s body. Hence, the motivation for making

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the combination would have been in order to enhance the manipulating ability of the device of Lemelson.

Claims 27-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Leschinsky et al (US Pat# 5,873,499). Lemelson meets the claim limitations as described above but fails to include a ratchet assembly, a threaded plunger or a lever-action handle.

However, Leschinsky discloses a dispensing gun that includes a plunger (92) that may be threaded, notched (ratchet) or grooved (ratchet). The gun also includes a handle (62) that has a trigger (104) and a pawl (108).

At the time of the invention, it would have been obvious to substitute the threaded plunger of Leschinsky for the actuation assembly and plunger of Lemelson; and the handle, trigger and pawl of Leschinsky for the control mechanism of Lemelson. Both prior art references are analogous in the implant dispenser art and are also analogous with the claimed invention; therefore, a combination is proper. Additionally, it is well known in the art that trigger mechanisms with threaded or ratcheted dispenser mechanisms are more stable than hand actuated dispensing mechanism, such as the one by Lemelson. Therefore, the motivation for the combination would have been in order to enhance the control of the dispensing of the implant of Lemelson thereby increasing the safety of the device to the patient.

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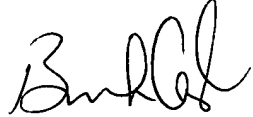
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams *CSW*
December 11, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700